

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,550	09/894,550 06/28/2001		Albert Collinson	BBC-083 A US	6240
959	7590	08/26/2002			
LAHIVE &		FIELD	EXAMINER		
28 STATE S BOSTON, M		10	ANDRES, JANET L		
BOSTON, IV	IA 0210	17			
				ART UNIT	PAPER NUMBER
				1646	
				DATE MAILED: 08/26/2002	g

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	09/894,550	COLLINSON ET AL.					
Office Action Summary	Examiner	Art Unit					
	Janet L Andres	1646					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute,  - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status	within the statutory minimum of thing apply and will expire SIX (6) MOI cause the application to become A	reply be timely filed  ty (30) days will be considered timely.  HTHS from the mailing date of this communication.  BANDONED (35 U.S.C. § 133).					
1) Responsive to communication(s) filed on	·						
	— s action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠ Claim(s) <u>1-88</u> is/are pending in the application							
4a) Of the above claim(s) is/are withdraw	vn from consideration.						
	Claim(s) is/are allowed.						
	Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.							
8) Claim(s) <u>1-88</u> are subject to restriction and/or e  Application Papers	election requirement.						
9) The specification is objected to by the Examiner							
10) The drawing(s) filed on is/are: a) accept		he Examiner					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C.	§ 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents	have been received.						
2. Certified copies of the priority documents	s have been received in A	opplication No					
<ul> <li>3. Copies of the certified copies of the prior application from the International Bur</li> <li>* See the attached detailed Office action for a list of the company of the company of the certified copies of the prior applied of the certified of the certified of the certified of the prior applied of the certified of the certified of the certified of the prior applied of the certified of the certif</li></ul>	eau (PCT Rule 17.2(a)).	•					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
<ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of	Summary (PTO-413) Paper No(s) Informal Patent Application (PTO-152) .					

## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-31, drawn to antibodies against IL-1 and methods of making them, classified in class 424, subclass 158.1.
- II. Claims 32-59, drawn to bispecific antibodies and methods of making them, classified in class 424, subclass 136.1.
- III. Claims 60-63, drawn to methods of detection of IL-1, classified in class 424, subclass 9.1.
- IV. Claims 64-69, drawn to methods of treatment with an antibody, classified in class 424, subclass 158.1.
- V. Claims 70-83, drawn to methods of generating recombinant antibodies, classified in class 424, subclass 801.
- VI. Claims 84-88, drawn to nucleic acids encoding antibodies and means of expression, classified in class 435, subclasses 69.1, 320.1, and 325, and class 536, subclass 23.5.

The inventions are distinct, each from the other because of the following reasons:

The methods and antibodies of group I are distinct from those of group II. Those of group II involve encompass molecules and methods not encompassed by group I and thus require a separate, non-coextensive search.

The methods of group I are not related to those of group III. They require different method steps and different reagents and have different goals and outcome measures. The antibodies of group I can be used for other purposes, such as inhibition.

Page 3

The methods of group I are not related to those of group IV. They require different method steps and different reagents and have different goals and outcome measures. The antibodies of group I can be used for other purposes, such as detection.

The methods and antibodies of group I are distinct from those of group V. Group V encompasses antibodies not encompassed by group I, and group I encompasses methods not encompassed by group V. The searches and considerations required are thus not coextensive.

The methods and antibodies of group I are not related to the nucleic acids of group VI. The molecules differ structurally and functionally and cannot be used together or interchangeable, and the methods require different reagents and have different method steps, different goals, and different outcome measures.

The methods of group II are not related to those of group III. They require different method steps and different reagents and have different goals and outcome measures. The antibodies of group II can be used for other purposes, such as inhibition and group II further encompasses antibodies that cannot be used for the methods of group III.

The methods of group II are not related to those of group IV. They require different method steps and different reagents and have different goals and outcome measures. The antibodies of group II can be used for other purposes, such as inhibition and group II further encompasses antibodies that cannot be used for the methods of group IV.

Application/Control Number: 09/894,550

Art Unit: 1646

The methods and antibodies of group II are distinct from those of group V. Group V encompasses antibodies not encompassed by group II, and group II encompasses methods not encompassed by group V. The searches and considerations required are thus not coextensive. The methods and antibodies of group II are not related to the nucleic acids of group VI. The molecules differ structurally and functionally and cannot be used together or interchangeable, and the methods require different reagents and have different method steps, different goals, and different outcome measures.

The methods of group III are not related to those of group IV. They require different method steps and have different goals and outcome measures.

The methods of group III are not related to those of group V. They require different reagents, have different method steps, and have different goals and outcome measures.

The methods of group III are not related to the methods and nucleic acids of group VI. The methods of group III cannot be used to generate or express the nucleic acids of group VI.

The methods of group IV are not related to those of group V. They require different reagents, have different method steps, and have different goals and outcome measures.

The methods of group IV are not related to the methods and nucleic acids of group VI. The methods of group IV cannot be used to generate or express the nucleic acids of group VI.

The methods of group V are not related to the methods of group VI. They require different method steps and have different goals and outcome measures. They are distinct from the nucleic acids of group VI because the nucleic acids can be generated in other ways, such as protein sequencing of antibodies and hybridization.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the searches required for the different groups are different, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: For Group I, the species are:

- a) antibodies against SEQ ID 1
- b) antibodies against SEQ ID 2
- c) antibodies against SEQ ID 3
- d) antibodies against SEQ ID 4

These sequences represent different molecules with different physical properties; antibodies generated with one would not have the same properties as antibodies against another and generation of one would not render generation of another obvious.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4 and 12-31 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

Application/Control Number: 09/894,550

Art Unit: 1646

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Application/Control Number: 09/894,550

Art Unit: 1646

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D. August 13, 2002

ÝVONNE EYLER, PH.D Supervisory patent examiner Technology center 1600 Page 6